

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE)
LITIGATION)

MDL NO. 1456
Civil Action No. 01-12257-PBS

THIS DOCUMENT RELATES TO)
01-CV-12257-PBS AND 01-CV-339)

Hon. Patti B. Saris

**THE JOHNSON & JOHNSON GROUP'S SUR-REPLY
MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION**

Table of Contents

	Page
Preliminary Statement.....	1
Plaintiffs’ Claims	1
A. Alleged Common Issue No. 1 – AWP “Inflation”.....	1
B. Alleged Common Issue No. 2 – “Secret” Price Incentives to PBMs.....	3
C. Alleged Common Issue No. 3 – “Harm” to the Class.....	4
D. J&J’s Oversight of its Operating Companies Does Not Demonstrate that Plaintiffs’ Claims Are Susceptible to Common Proof.....	5
Conclusion	6

Preliminary Statement

Because the J&J defendants are decentralized and diverse, plaintiffs' claims against them cannot possibly be tried using common, class-wide proof. Johnson & Johnson itself does not even sell pharmaceuticals. Its individual operating companies develop and implement their own pricing and marketing strategies with respect to each of the 36 drugs at issue.

Plaintiffs respond that these myriad differences – most of which they do not dispute – are “red herrings.” *Pl. Reply Br.* at 1. They say they will present “common proof” on three so-called “core issues”: (1) whether the J&J companies “deliberately inflated and controlled” AWP, (2) whether they paid “substantial and undisclosed rebates and administrative fees” to PBMs, and (3) whether the putative class “was harmed.” *Id.*

This is simplistic, and it misstates the case.

Plaintiffs' Claims

This lawsuit is not just about the three, cherry-picked issues identified in plaintiffs' reply brief. Plaintiffs are complaining about a host of marketing and pricing practices, including the “promotion” of reimbursement rates, encouraging physicians to bill for “free samples,” and conspiring with PBMs to prevent them from disclosing rebates to their clients. *See, e.g., AMCC*, ¶¶ 6-7, 159-67. Of course, having taken considerable discovery of the J&J defendants, plaintiffs offer no proof that the J&J companies did any of these things. Implicit in their silence is the fact that these issues are not susceptible to common proof. But, as set forth below, even the three issues identified in plaintiffs' reply brief are not susceptible to common proof.

A. Alleged Common Issue No. 1 – AWP “Inflation”

Plaintiffs say the relationship between AWP and WAC is a “core issue” susceptible to “common proof.” Plaintiffs ritualistically characterize the difference between WAC and AWP as “AWP inflation.” *E.g., Pl. Reply Br.* at 1, 2.

This is not a core issue, and it never was. Indeed, plaintiffs now concede that the “spread” between AWP and WAC is known because it is published by the various pricing

reporters, including First Data Bank and Redbook. The publicly-reported AWP for most J&J company drugs is 120% the drug's publicly-reported WAC price. The exception is the AWP for Remicade, which is listed at 130%. None of this is secret. In fact, as plaintiffs' expert, Dr. Schondelmeyer, admits, AWP is not intended to reflect "adjustments for discounts, rebates, purchasing allowances or other forms of economic consideration."¹ This fact has been known for more than a decade.²

In the face of this public knowledge, plaintiffs abandoned the claim that a drug's AWP was inflated if it was higher than the "average" price charged by wholesalers. Plaintiffs' other expert, Dr. Hartman, now theorizes that AWP is some sort of "signal," and that payors "expect" that a drug's AWP will be 16% to 33% higher than the average of its actual selling prices to all classes of trade other than the government.³ The implication of this theory is that AWP is not "inflated" if it does not exceed ASP by more than 33%.

Plaintiffs do not say whether they will adduce common proof that the AWP for the J&J company drugs are "inflated" using Dr. Hartman's theory as a yardstick. Indeed, despite receiving reams of J&J pricing data in discovery, plaintiffs have not submitted a single spread calculation for any of the 36 drugs at issue.

During the tutorial last December, plaintiffs' counsel tried to suggest that one J&J company engaged in a very different kind of AWP "inflation." Apparently hoping that his question would be a surrogate for proof, counsel asked defendants' tutorial expert, Dr. Bell, if he knew that J&J simultaneously increased the AWP and lowered the WAC on Flexeril®, a medication used to treat lower back pain. As set forth in the annexed declaration of Mr. Rock Magnotta, counsel's question was unfounded. The company that sells Flexeril never raised its

¹ Declaration of Stephen W. Schondelmeyer in Support of Plaintiffs' Motion for Class Certification, September 2, 2004, at 32.

² See, e.g., Health Econ. Program, Minn. Dep't of Health, *Prescription Drug Study: A Report to the Minnesota Legislature on the Prescription Drug Market* (April 1994) (Exhibit 2 to Decl. of William F. Cavanaugh, Jr. in Support of the Track 1 Defs' Mem. in Opp. to Class Certification).

³ Declaration of Raymond S. Hartman In Support of Plaintiffs' Motion for Class Certification, September 3, 2004, at 45-46.

AWP while simultaneously lowering its WAC price. Magnotta Decl., ¶ 3 (Sur-reply App., Tab 1).

Counsel tried the same tactic with respect to another drug – Remicade. He asked Dr. Bell if he knew that Centocor paid a substantial rebate to physicians on Remicade. Dr. Bell responded that he was not aware of that. This question was also unfounded. As set forth in the attached declaration of Mr. John Hoffman, Centocor never pays rebates to physicians. Hoffman Decl., ¶ 6 (Sur-reply App., Tab 2).

B. Alleged Common Issue No. 2 – “Secret” Price Incentives to PBMs

Plaintiffs next argue that common proof will establish that “J&J provided substantial undisclosed rebates and administrative fees to PBMs on their oral drugs.” *Pl. Reply Br.* at 1.⁴ But most of the 33 oral drugs at issue are not covered by PBM rebate contracts. Indeed, plaintiffs say that only 12 of J&J’s oral drugs are listed on PBM contracts. *Pl. Reply Br.* at 4. That leaves 21 oral drugs that are not covered.

Despite this obvious (and dispositive) difference, plaintiffs say they can prove their PBM claim using common proof because PBM contracts are administered by a single J&J company, rather than by the individual operating companies that actually participate in PBM contracts. But the manner in which the PBM contracts are *administered* is irrelevant. The operating companies themselves, acting unilaterally, make the decision whether to pay rebates to a PBM, and if so, how much to pay, and on which drugs. Maffie Tr. 185-88 (Sur-reply App., Tab 3).

Plaintiffs accuse the J&J companies of “conspiring [with PBMs] to hide drug discounts from Class members.” *Pl. Reply Br.* at 4. They attach testimony from Robert Spurr, an Ortho-McNeil witness who allegedly said that “administrative fees” are confidential. *Id. citing* Spurr Tr. 231-32, Pl. Ex. 3. Mr. Spurr said nothing of the sort, a fact that can be readily confirmed by reading the testimony cited in plaintiffs’ reply brief. *Id.* In any event, the fact that PBMs receive administrative fees for their services is widely known. The Medicare safe harbor rules explicitly

⁴ Plaintiffs’ PBM claim is noteworthy in part because it does not apply to the two largest-selling J&J company products in the case, Remicade and Procrit, since neither of these is an “oral drug.”

allow payment of administrative fees up to three percent. 42 C.F.R. §1001.952(j) (2005). Because J&J companies never pay more than the safe harbor amount, the *maximum* administrative fee that a PBM might receive is a matter of public record. *See* Tab 3, Maffie Tr. 107-17.

Finally, plaintiffs say that the “J&J companies worked with PBMs to deliberately conceal the amount of rebates and administrative fees.” *Pl. Reply Br.* at 4. This flatly misstates the evidence. Indeed, the confidentiality provision that plaintiffs attach to their reply brief *allows* the PBM to share pricing information with its customers. *See* Pl. Ex. 12; *c.f.* Pl. Ex. 7 at 257 (confidentiality applies to other PBMs). More recent contracts *require* PBMs to disclose the rebates they receive on J&J products. Tab 3, Maffie Tr. 182-83.

C. Alleged Common Issue No. 3 – “Harm” to the Class

Plaintiffs identify “harm” to the class as the third issue susceptible to common proof, but then say nothing more about it. *Pl. Reply Br.* at 1. This is hardly surprising. The different business practices among the J&J operating companies preclude common proof of class-wide harm.

Compare, for example, Ortho Biotech’s practices with respect to Procrit, with Centocor’s practices with respect to Remicade. Ortho Biotech offers rebates to physicians, but Ortho Biotech’s sales force is strictly prohibited from discussing whether the physician can earn a profit or margin by administering the drug. Hiriak Tr. 99-103; 107-11 (Sur-reply App., Tab 4); Pearson Tr. 314-316 (Sur-reply App., Tab 5). Ortho Biotech opposed AWP-based reimbursement and actively lobbied CMS to scrap the AWP system in favor of a reimbursement model based on average selling price. Tab 5, Pearson Tr. 226, 234-36.

Centocor does not pay rebates to physicians, but Centocor’s sales force is permitted to discuss the amount of reimbursement. This practice stems from the fact that, when Remicade was launched, the physicians who were being asked to administer Remicade (typically gastroenterologists and rheumatologists) had almost no experience infusing drugs in their offices.

Because in-office administration requires the physician to pay for special infusion equipment, staff time and office space, physicians needed to know whether infusing Remicade made economic sense. The alternative was to send the patient to a hospital where infusions cost more. By moving the site of patient care from the hospital to the physician's office, Centocor's practice *reduced* reimbursement costs. Tab 2, Hoffman Decl., ¶ 7; Hoffman Tr. 226-28, 239-41 (Sur-reply App., Tab 6).

D. J&J's Oversight of its Operating Companies Does Not Demonstrate that Plaintiffs' Claims Are Susceptible to Common Proof

Plaintiffs' last point is that J&J's alleged "knowledge and approval" of each company's pricing and marketing practices somehow demonstrates that the J&J defendants' practices are susceptible to common proof. This is neither logical nor correct.

Ms. Christine Poon, J&J's Worldwide Chairman for all of its pharmaceutical operating companies, testified that pricing decisions are made by the product managers at the operating companies. Poon Tr. 20, 70-73 (Sur-reply App., Tab 7). Ms. Poon approves price change proposals and she sometimes asks questions to satisfy herself that a proposed price change "is the right thing to do." *Id.* Even so, it is "not part of [J&J's] culture to have a lot of people trying to second guess the operating companies." *Id.* No one at J&J besides Ms. Poon is involved in approving price changes. *Id.* at 85.

Ms. Poon approves changes in the WAC price, not the AWP. *Id.* at 19. AWP is never even discussed. *Id.* Rather, it's an "automatic calculation" made from the list price. *Id.* No operating company has ever proposed changing the standard markup to anything other than 20%, so Ms. Poon has not had occasion to think about whether such a thing would be possible. *Id.* at 21-22. J&J does not have policies or instructions pertaining to AWP. *Id.* at 19.

Plaintiffs note that various J&J operating companies have worked together to develop and implement strategies pertaining to PBMs and other managed care customers. *Pl. Reply Br.* at 7. While some operating companies have coordinated their efforts in the managed care market,

none of these efforts have anything to do with AWP or any other aspect of plaintiffs' case. *Id.*, Pl. Ex. 14.

Finally, plaintiffs refer to two J&J entities known as the Global Pharmaceutical Marketing Committee and the PGSM Health Economics Group. *Pl. Reply Br.* at 7. The first entity provides advice concerning worldwide launch prices for new drugs. Tab 7, Poon Tr. 92-93. There is no evidence it was involved in helping to determine the price of any of the drugs at issue in this case. *See id.* at 99; Spurr Tr. 66-67 (Sur-reply App., Tab 8). The second entity offers advice concerning "competitive activities" and the "political environment" in the U.S. and in other countries. Tab 7, Poon Tr. 77. The operating companies are not required to solicit PGSM's input, and there is no evidence that PGSM's advice, when solicited, has anything to do with AWP. *Id.* at 78-79.

In short, contrary to plaintiffs' claim, J&J does not have an "organization-wide and centrally controlled ... policy of manipulating AWP's." *Pl. Reply Br.* at 7. Rather, J&J is decentralized and diverse. The claims against the J&J defendants are not susceptible to common proof.

Conclusion

Plaintiffs' class certification motion should be denied as to the companies in the J&J Group.

Respectfully submitted,



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Dated: January 21, 2005

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